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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,783	06/27/2003	Sanjay Kumar Nigam	15670-053001 / SD2001-205	8109
41790	7590	11/06/2006	EXAMINER	
BUCHANAN, INGERSOLL & ROONEY LLP P.O. BOX 1404 ALEXANDRIA, VA 22313-1404			FORD, ALLISON M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/608,783

Applicant(s)

NIGAM ET AL.

Examiner

Allison M. Ford

Art Unit

1651

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 October 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☒ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: 1.
Claim(s) rejected: 1-7.
Claim(s) withdrawn from consideration: 8-67.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

Continuation of 3. NOTE: Applicant's proposed amendments include new limitations to the independent claims which would require a new search and consideration. Specifically, applicants have proposed amending claims 1 and 3 to require the culture medium, in which the UB cells are cultured, to not have been previously elaborated with cells derived from metanephric mesenchyme and to not contain detectable levels of pleiotrophin; this limitation is in direct contrast to what was previously claimed: that the culture medium comprised BSN culture medium, which is culture medium derived from metanephric mesenchymal cells- which inherently contains pleiotrophin. It is noted claim 3 specifically states "culturing the isolated ureteric bud tissue ...in the presence of a culture medium comprising pleiotrophin..." followed by "...wherein the culture medium ...does not contain detectable levels of pleiotrophin..." The added limitation renders the claims indefinite, and may raise new issues under written description and new matter, as there is no support in the specification for the negative limitations.

Continuation of 11. does NOT place the application in condition for allowance because: the arguments are not found persuasive for the following reasons:

In response to the objection to claim 1, the amendment to the claims has not been entered, and so the claim remains rejected.

In response to the rejection of claims 3-7 as lacking written description for active fragments of pleiotrophin and heregulin and for functional equivalents of FGF-1 and GDNF, applicants submit references to show that the active fragments of pleiotrophin and heregulin and that the function of FGF-1 were known at the time the invention was made, applicants state these references demonstrate that the active fragments were known, and thus they were not required to specifically restate them in the instant application. It is noted that the written description requirement was first set forth in the first non-final office action, and then maintained in the final rejection; therefore applicants had opportunity to present the work as evidence previously in prosecution. Because applicants have failed to provide a showing of good and sufficient reasons why this evidence was not presented earlier, entrance of the submission after final is not appropriate. Therefore, the evidence relied upon (Zhang et al, 1999, Barbacci et al, 1995, Hsu et al, 1997) are not being considered, and the rejection stands for the reasons of record.

In response to the rejection of claims 1-7 as lacking enablement for inducing UB cells to undergo branching morphogenesis in culture medium comprising only heregulin, applicants submit a post-filing date references (Sakurai et al, 2005) to demonstrate enablement. However, as stated above, because the enablement rejection was set forth in the initial office action, submission of evidence after final is not appropriate without a showing of good and sufficient reason why the evidence was not presented previously; therefore the evidence is not entered. However, it is further pointed out that applicants cannot rely on post-filing date art to show enablement for their method at the time the invention was filed.

In response to the rejection of claims 1-7 under 35 USC 112, second paragraph, applicants argue they have amended the claims to obviate the indefiniteness rejections, but since the proposed amendments have not been entered, the claims remain rejected for the reasons of record.

In response to the rejection of claims 1, 3, 6 and 7 under 35 USC 103(a) over Sakurai et al (PNAS, 1997) in view of Current Protocols in Cell Biology and Naughton et al, applicants continue to argue that the examiner relied on improper hindsight, and had no motivation to combine the references. It is noted that these same arguments were addressed in the final office action (Pages 17-19), in order to not burden the record, applicants are directed to those pages of the final rejection for response to the arguments.

In response to the rejection of claims 1, 3, 4, 6 and 7 under 35 USC 103(a) over Qiao et al, in view of Current Protocols in Cell Biology and Naughton et al, it is first noted that applicants did not previously present traverse this rejection in response to the non-final office action; therefore the arguments presented after final are new, however, they will be briefly addressed:

Applicants argue that Qiao et al fails to identify the specific factors which are required for branching morphogenesis in kidney tissue, and in fact teaches away from heparin binding proteins less than 100 kDa. Applicants argue the examiner has otherwise relied on improper hindsight to construct the rejection of record.

These arguments are not found persuasive. First, it is noted that the rejected claims do not specify the specific factors within the culture medium, but rather only require a culture medium that comprises heregulin and/or pleiotrophin. Qiao et al uses the same BSN-culture medium; though they suggest a different weight protein as a possible key morphogenic factor, this does not constitute teaching away, because the claims do not specify any isolated fraction, or protein weight. Second, regarding improper hindsight, it is again pointed out that the rejected claims do not require isolated heregulin or pleiotrophin, but rather only require a culture medium which COMPRISES one or both of these proteins, BSN culture medium, used by Qiao et al, inherently comprises both heregulin and pleiotrophin; therefore no hindsight reconstruction was relied upon.



LEON B. LAWFORD, JR.
PRIMARY EXAMINER